

REMARKS

Upon entry of this amendment, claims 1, 3-16, 18-35 and 38-39 are pending in the application. Claims 1 and 16 are independent claims drawn to a sugar free composition, while claim 38 is an independent claim drawn to an oral hygiene product and claim 39 is an independent claim drawn to a weight reduction or cholesterol reducing product, respectively. The remaining claims depend from claims 1 or 16. Claims 2, 17, 36 and 37 have been canceled without prejudice or disclaimer to the subject matter contained therein. Claims 1, 28-30 and 38-39 have been amended to clarify the subject matter contained therein.

Claims 1-27, 29-35, 38 and 39 stand rejected as being anticipated by U.S. Patent No. 4,963,359 to Haslwanter et al. Claims 1-35 and 38-39 stand rejected as being obvious over the '359 patent. And, Claims 1-35 and 38-39 stand rejected as being obvious over U.S. Patent No. 4,911,937 to Crosello et al.

Applicants respectfully traverse these rejections and respectfully request reconsideration and withdrawal thereof.

1. Rejection of Claims 1-27, 29-35, 38 and 39

Under 35 U.S.C. 102(b)

Claims 1-27, 29-35, 38 and 39 stand rejected under 35 U.S.C. 102(b) as being anticipated by Haslwanter et al. (U.S. Patent No. 4,963,359) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and respectfully requests reconsideration and withdrawal thereof.

To establish an anticipation rejection, every claimed element must be found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. V. Union Oil Co. of California*, 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); See also, MPEP § 2131. Applicant respectfully submits that the Examiner has not met this burden.

Independent claim 1 is drawn to a sugar-free composition comprising: a mixture of at least two polyols present in an amount from about 15 to 80% by weight, with the polyols being selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof; an emulsifier system

present in an amount from about 1.0 to 30% by weight; an active agent in an amount from about 0.1 to 70% by weight; water in an amount from 0 to 15% by weight; and optional components comprising colors, flavors and binders, wherein said ingredients in said sugar-free composition are present in an amount totaling 100%. Likewise, independent claim 16 is drawn to a protein-based, sugar-free composition comprising a mixture of: a mixture of at least one protein and at least one polyol present in an amount from about 20 to 99% by weight, with the polyols being selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof; an emulsifying system present in an amount from about 1.0 to 30% by weight; an active agent in an amount from about 0.1 to 70% by weight; and water in an amount from 0 to 10% by weight. Claims 38 and 39 also contain the limitations, *inter alia*, of at least two polyols and an emulsifier system. The remaining claims depend from either claim 1 or 16, and therefore contain all of the limitations found therein.

Thus, in order for Haslwanter et al. to anticipate claims 1, 16, 38 and 39 (and therefore, the claims that depend therefrom) Haslwanter et al. must disclose all of the limitations set forth above. In particular, Haslwanter et al. must disclose **the presence**

of two polyols (or a protein and a polyol with respect to claim 16) selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof. **In addition, the polyols must be present in the amounts as claimed within each respective claim.** Applicants respectfully submit that Haslwanter et al. fail to do so, and therefore do not anticipate the claims.

Haslwanter et al. disclose a non-cariogenic confectionary based **free of cellulosics and graining compounds.** The base contains hydrogen starch hydrolysates and at least one edible oil, fat, wax or mixtures thereof and an emulsifier. However, Applicants respectfully submit that Haslwanter **does not disclose** the presence of **at least two or more polyols,** as is claimed in the present claims. Hydrogen starch hydrolysate is the only claimed polyol used within the Haslwanter et al. patent in its **pure** state.

The Examiner argues that Haslwanter teaches two polyols due to the presence of hydrogen starch hydrolysate and glycerin and/or sorbitol. The Examiner points to a listing of possible humectants as a basis for this assertion. However, as can be seen above, Applicants have incorporated the list of possible polyols to be selected from into claim 1, with glycerin having been removed from the list. In addition, the present claim calls for sorbitol, **not**

an aqueous solution of sorbitol, as is discussed by Halswanter.

Applicants respectfully submit that an aqueous solution of sorbitol **is not sorbitol itself**. In other words, an aqueous solution of sorbitol is a different entity than pure sorbitol. In fact, by definition, an **aqueous solution** of sorbitol **also contains water**, and thus is not just sorbitol itself. As a further basis for this submission, Applicants direct the Examiner's attention, again, to the specification of Haslwanter et al. In particular, in column 5, line 65 to column 6, line 7, Haslwanter et al. explicitly state that "it is a special feature of this invention that the non-cariogenic confectionery bases and compositions of this invention are free of, i.e. **contain no**, graining compounds such as the crystalline **sugar alcohols, mannitol, xylitol, sorbitol and the like**...The term 'graining compounds' means substances added in the form of crystalline solids to promote crystallization, i.e. act as a seeding compound and to control crystal size in the confectionery products." (Emphasis added). Thus, in order to reconcile the apparent contradiction (first Haslwanter et al. teach that no sugar alcohols are added, then the patent teaches that **an aqueous solution** of sorbitol is used as a humectant), the aqueous solution of sorbitol **must be different than the sorbitol discussed in the first part of the patent**. Therefore, the aqueous solution of

sorbitol is **not** the same sorbitol as is presently claimed in the independent claims of this application.

Furthermore, Applicants again reiterate the previous argument with respect to claims 10-11 and 25-26, namely that these claims add the limitations of a bioadhesive agent selected from a group of cellulose and other materials, which again, Haslwanter et al. teach away from. In particular, Haslwanter et al. state in column 6, lines 8-10, that it is a **special feature** of the compositions of the patent that they **contain no cellulose**. This explicitly teaches away from the claimed invention found in claims 10-11 and 25-26.

Therefore, Applicants respectfully submit that Haslwanter et al. fail to teach each and every claimed limitation in the independent claims (and also the dependent claims), and the Examiner has thus failed to prove that the claims are anticipated by the patent.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims as being anticipated by Haslwanter et al.

2. Rejection of Claims 1-35 and 38-39 Under 35 U.S.C. 103(a)

Claims 1-35 and 38-39 stand rejected under 35 U.S.C. 103(a) as

being obvious over Haslwanter et al. (U.S. Patent No. 4,963,359) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The reference of record, Haslwanter et al., does not teach or suggest Applicants' inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference which would lead the ordinary skilled artisan to modify the reference to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and

(3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

Independent claim 1 is drawn to a sugar-free composition comprising: a mixture of at least two polyols present in an amount from about 15 to 80% by weight, with the polyols being selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof; an emulsifier system present in an amount from about 1.0 to 30% by weight; an active agent in an amount from about 0.1 to 70% by weight; water in an amount from 0 to 15% by weight; and optional components comprising colors, flavors and binders, wherein said ingredients in said sugar-free composition are present in an amount totaling 100%.

Likewise, independent claim 16 is drawn to a protein-based, sugar-free composition comprising a mixture of: a mixture of at least one protein and at least one polyol present in an amount from about 20 to 99% by weight, with the polyols being selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof; an emulsifying system present in an amount from about 1.0 to 30% by weight; an active agent in an amount from about 0.1 to 70% by weight; and water in an amount from 0 to 10% by weight. Claims 38 and 39 also contain the limitations, *inter alia*, of at least two polyols and an emulsifier system. The remaining claims depend from either claim 1 or 16, and therefore contain all of the limitations found therein.

Applicants respectfully submit that Haslwanter et al. fail to render obvious these claims, as Haslwanter et al. fail to teach every limitation found in the claims and offers no motivation or teaching to modify the reference in an attempt to achieve the claimed subject matter.

As is discussed above with respect to the anticipation rejection, Applicants respectfully submit that the present claims call for sorbitol, **not an aqueous solution of sorbitol**, as is discussed by Halswanter. Applicants again respectfully submit that

an aqueous solution of sorbitol **is not sorbitol itself**. In other words, an aqueous solution of sorbitol is a different entity than pure sorbitol. In fact, by definition, an **aqueous solution** of sorbitol **also contains water**, and thus is not just sorbitol.

Applicants further reiterate this position is taken from the text of the Haslwanter et al. patent. Applicants direct the Examiner's attention, again, to the specification of Haslwanter et al. In particular, in column 5, line 65 to column 6, line 7, Haslwanter et al. explicitly state that "it is a special feature of this invention that the non-cariogenic confectionery bases and compositions of this invention are free of, i.e. **contain no**, graining compounds such as the crystalline **sugar alcohols, mannitol, xylitol, sorbitol and the like**...The term 'graining compounds' means substances added in the form of crystalline solids to promote crystallization, i.e. act as a seeding compound and to control crystal size in the confectionery products." (Emphasis added). Thus, in order to reconcile the apparent contradiction (first Haslwanter et al. teach that no sugar alcohols are added, then the patent teaches that **an aqueous solution** of sorbitol is used as a humectant), the aqueous solution of sorbitol **must be different than the sorbitol discussed in the first part of the patent**. Therefore, the aqueous solution of sorbitol is **not** the

same sorbitol as is presently claimed in the independent claims of this application.

The Examiner states that the Applicants are arguing limitations not found in the claims. Applicants respectfully disagree with the Examiner. Applicants have pointed out that Haslwanter et al. teach **away from using graining sugar alcohols** in their product, but do include **an aqueous solution of sorbitol** as an humectant. Thus, in order for the Haslwanter patent to make any sense whatsoever, one of ordinary skill in the art would come to the conclusion that **sorbitol and an aqueous solution of sorbitol are not the same entity**. The independent claims each claim **sorbitol (a limitation found in the claims)**, which is **not** the same as an **aqueous** solution of sorbitol. Nor would one of ordinary skill in the art deem them to be the same. Thus, Applicants **are** arguing differences between limitations **found in the claims** and not found in the prior art.

Therefore, Applicants respectfully submit that Haslwanter et al. fail to teach each and every claimed limitation in the independent claims (and also the dependent claims), and that there is no motivation within Haslwanter et al. to modify it in an attempt to achieve the presently claimed subject matter as Haslwanter et al. actually teach away from the present claims.

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Thus, the Examiner has failed to meet the burden of proving a *prima facie* case of obviousness.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims as being anticipated by Haslwanter et al.

3. Rejection of Claims 1-35 and 38-39 Under 35 U.S.C. 103(a)

Claims 1-35 and 38-39 stand rejected under 35 U.S.C. 103(a) as being obvious over Crosello et al. (U.S. Patent No. 4,911,937) for the reasons set forth in the Office Action.

RESPONSE

Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

The reference of record, Crosello et al., does not teach or suggest Applicants' inventive subject matter as a whole, as recited in the claims. Further, there is no teaching or suggestion in this reference which would lead the ordinary skilled artisan to modify the reference to derive the subject matter as defined in the amended claims.

The U.S. Supreme Court in *Graham v. John Deere Co.*, 148 U.S.P.Q. 459 (1966) held that non-obviousness was determined under § 103 by (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and, (4) inquiring as to any objective evidence of nonobviousness.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

Independent claim 1 is drawn to a sugar-free composition

comprising: a mixture of at least two polyols present in an amount from about 15 to 80% by weight, with the polyols being selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof; an emulsifier system present in an amount from about 1.0 to 30% by weight; an active agent in an amount from about 0.1 to 70% by weight; water in an amount from 0 to 15% by weight; and optional components comprising colors, flavors and binders, wherein said ingredients in said sugar-free composition are present in an amount totaling 100%. Likewise, independent claim 16 is drawn to a protein-based, sugar-free composition comprising a mixture of: a mixture of at least one protein and at least one polyol present in an amount from about 20 to 99% by weight, with the polyols being selected from the group consisting of hydrogenated starch hydrolysate, isomalt, erythritol, polydextrose, maltitol, lactitol, sorbitol, xylitol, mannitol and mixtures thereof; an emulsifying system present in an amount from about 1.0 to 30% by weight; an active agent in an amount from about 0.1 to 70% by weight; and water in an amount from 0 to 10% by weight. Claims 38 and 39 also contain the limitations, *inter alia*, of at least two polyols and an emulsifier system. The remaining claims depend from either claim 1 or 16, and therefore contain all

of the limitations found therein.

Applicants respectfully submit that Crosello et al. fail to render obvious these claims, as Crosello et al. fail to teach every limitation found in the claims and offer no motivation or teaching to modify the reference in an attempt to achieve the claimed subject matter. Further, Applicants submit that, **at the time of the invention**, one of ordinary skill in the art would not be led by Crosello et al. to modify its teachings in an attempt to achieve the present invention. The requirement "at the time the invention was made" is to avoid impermissible hindsight. MPEP 2141.01(III). Further, "in determining the differences between the prior art and the claims, the question under 35 USC 103 is no whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP 2414.02 citing *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). (Emphasis in original). In addition, Applicants reiterate that MPEP §2141.02 says that "[a] prior art reference **must be considered in its entirety, i.e., as a whole**, including positions that would lead away from the claimed invention." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S.

851 (1984). (Emphasis added and in original).

Crosello et al. disclose a chewable, peelable nougat candy. The candy comprises at least two layers of nougat wherein each layer of nougat is made separable from the adjoining layer of nougat by the interposition of a compound coating. "Nougats are aerated confectionery compositions, **well known in the art**, which have a relatively high moisture content." (Col. 5, l. 37-39, emphasis added). Nougats have a density that "largely depends on a **frappe element** and texture on a syrup element along with its subsequent crystallization." (Col. 8, l. 47-50, emphasis added). Thus, Crosello et al. disclose confectionery compositions **that are aerated** in order to obtain their desired consistency and density.

Reviewing the present claims **as a whole**, along with the Crosello et al. patent **as a whole**, Applicants respectfully submit that one of ordinary skill in the art **at the time of the invention** would not have been motivated to modify the teachings of Crosello et al. in an attempt to achieve the present claims. Crosello et al., as is highlighted above, acknowledge that aerated confectionery compositions are well known in the art. As such, Applicants respectfully submit that one of ordinary skill in the art **would not look to a document that teaches aerated products to produce a non-aerated product.**

The Examiner indicates where various limitations of the present claims might be found in the Corsello et al. patent. However, Applicants respectfully submit that there is no motivation within Corsello et al. to take the individual limitations and attempt to combine them to achieve the presently claimed invention. Taken as a whole, the reference is directed to an **aerated** confectionery product, which is different from the present invention. The Examiner relies on one sugarless example within the patent to reject the claims, arguing that it would have been obvious to change the weight percentages in order to attempt to achieve the present claims. Even this example, though, **is directed to an aerated confectionery composition**. One of skill in the art of confectionery compositions would not attempt to make the nougats of Corsello et al. **without the frappe (aerated) component**. In other words, there is no motivation to leave the frappe component out of the Corsello et al. patent. Thus, it would not be feasible for one of skill in the art to achieve the present claims based on the teachings of Corsello et al.

Therefore, Applicants respectfully submit that there is no motivation within Corsello et al. to modify it in an attempt to achieve the presently claimed subject matter as the Corsello et al. patent is directed to a wholly different invention than the present

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claims. Thus, the Examiner has failed to meet the burden of proving a *prima facie* case of obviousness.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims as being anticipated by Corsello et al.

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to reconsider and withdraw the all pending rejections, and to allow all of the claims pending in this application.

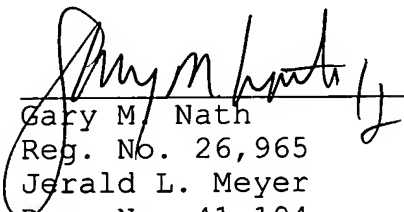
If the Examiner has any questions or comments regarding this matter, he is welcomed to contact the undersigned attorney at the below-listed number and address.

Respectfully submitted,
NATH & ASSOCIATES

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